APPLICANTS: Hoffman, Andrew M.
SERIAL NUMBER: 09/616,483

REMARKS

Applicant thanks the Examiner for the telephone conference of May 13, 2003, in which the present claim amendments were discussed.

Claims 1 and 3-22 are pending. Claim 2 has been canceled. Claims 1 and 6 were amended to more clearly described the claimed subject matter, i.e., the device is sized to cover only one nostril (and not another nostril) of an animal.

The amendment to claims 1 and 6 is supported by disclosure in Figs. 2A-D and page 6, lines 1-7, of the specification. Claims 19-20 were amended to require particle delivery to small airways of the lung; the amendment is supported by disclosure at page 2, line 25, to page 3, line 4, of the specification.

No new matter has been added by this amendment.

35 U.S.C. § 102

Claims 1-3, 6-18 and 22 were rejected for anticipation by Crain (USPN 3,812,853).

In responding to Applicant's previous response, the Examiner stated:

> The Examiner would like to point out that the limitation in claim 1 with respect to "for enclosing one external nare" does not limit the device to only or just one external nare.

Applicant has further amended the claims to clarify the scope. Amended claim 1 now requires a cup-shaped body for enclosing only one external nare and that the device contain an interfacing lumen the diameter of which does not enclose a second external nare of a mammal.

The Crain reference describes and shows a nose piece 12, which receive the nose of the user. Fig. 1 and Fig. 3 of the Crain reference show diameter of the nose piece 12 encircling both

nostrils. The entire nose is received by the nose piece 12, and Crain's device therefore has a vent hole 12 "to enable the user to inhale with his nose inserted into the nose piece 12" (col. 3., lines 54-57, of Crain). In contrast, the claimed device covers only one nostril. Therefore, the amended claims are not anticipated by the Crain reference.

35 U.S.C. § 103

Claims 4 and 5 were rejected for obviousness over Crain in view of Foley et al. (USPN 5,988,160). The Examiner stated:

> As to claims 4 and 5, Crain teaches essentially all of the limitations except for wherein the device comprises a patient-actuated unidirectional inhalation valve. However, Foley does teach a patient-activated unidirectional inhalation valve so that air is retained for a second inhalation and medicament is not wasted.

Applicant's amendment of claim 1 unambiguously distinguishes the claimed subject matter from the primary reference, Crain, by requiring a device with a shape that encloses only one nostril of an animal. The secondary reference, Foley, does not describe or suggest a shape or device configuration other than one that encloses both nostrils of an animal. In view of the amendment to claim 1, Applicants submit that claims 4 and 5 are nonobvious over the cited combination of references.

Claims 19, 20, and 21 were rejected for obviousness over Crain. With respect to these claims, the Examiner stated:

> Crain fails to specifically teach the limitations with respect to the particle size and the type of medicament. However, such a limitation depends on the intended user along with the intended therapy and the type of medicament used (for particle size). Furthermore, such a limitation may be arrived through routine experimentation and observation.

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Claims 19, 20, and 21 are drawn to a method of delivering a medicament in a single inhaled breadth of an animal using the device of claim 1, which device covers only one nostril of the animal. Claims 19 and 20 have been amended to specify delivery to small airways of the lung. Earlier devices, such as that described by Crain, cannot maintain the small particle size of drugs to be administered to small airways.

Claims 19-21 are not obvious over Crain, because although initial particle size is determined by the "type of medicament used", other devices cannot maintain the small particle size of drugs required for effective delivery to a clinically relevant anatomical site, i.e., the small airways of the lung. Condensation and clumping of particles due to exposure of the drug to moisture (which condenses due to rebreathing in a device such as Crain's nosepiece design) leads to particles that are too large to gain access to small airways of the lung. Particles larger than about 20 microns, such as those generated by vaporizers, some nebulizers, and following clumping of particles after exposure to moisture in a mask or rebreathing chamber device, are not effectively delivered to small airways of the lung (page 2, line 25, to page 3, line 4, of the specification).

The claimed method represents a significant improvement and advantage over earlier methods. Unlike other devices that cover both nostrils and/or include a rebreathing chamber, the claimed method using the claimed single nostril design and a single inhalation method ensures that drug particles (aerosolized or dry powder) are effectively delivered in a small particle size to target airways of the lung to achieve clinical benefit.

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CONCLUSION

On the basis of the foregoing amendments and remarks, Applicant respectfully submits that the pending claims are in condition for allowance.

Applicant files concurrently herewith a petition for a three (3) month extension of time. With the extension, this amendment is due on or before May 14, 2003. The Commissioner is hereby authorized to charge any required fees, or credit any overpayment, to Deposit Account No. 50-0311 (Reference No. 21629-001).

Respectfully submitted,

Ingrid A. Beattie, Reg. No. 42,306
Attorney for Applicant
c/o MINTZ LEVIN
One Financial Center
Boston, Massachusetts 02111
Tel.: (617) 542 6000
Fax: (617) 542-2241